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10/565,085	01/17/2006	Shigeru Nemoto	KITO9.001APC	5452
20995 7590 06/13/2011 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER IMPINK, BRADLEY GERALD	
			ART UNIT 4189	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/565,085	Applicant(s) NEMOTO, SHIGERU	
	Examiner BRADLEY IMPINK	Art Unit 4189	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/09/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14-16 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14-16 and 21-28 is/are rejected.
- 7) ☒ Claim(s) 7, 22 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/07, 09/23/08, 07/09/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' cancellation of claims 10-13, 17-20 and 29-32 and amendments to claims 5-9, 14, 21-23, 25, 27 and 28 in the preliminary amendment submitted 01/17/2006 are acknowledged and have been entered.

Priority

2. This application was filed on 01/17/2006 as a 371 of PCT/JP04/09637 filed 07/07/2004 and claims benefit of Japanese Patent Application Number 2003-276639 filed on 07/18/2003. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

3. Regarding the reference to Japanese patent application numbers 2002-099928 and 2003-098057 on page 4, line 10-11, the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the condition correcting means, coefficient storing means, coefficient reading means, body entering means, type entering means, concentration storing means, concentration reading means, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "118" has been used to designate both ultrasonic motors (first appearing on page 12, line 16) and sub operation panel (first appearing on page 13, line 1); "116" has been used to designate both front face of main body housing (first appearing on page 11, line 16) and cylinder holding mechanism (first appearing on page 11, line 22); and "1000" has been used to designate both the liquid injection system (first appearing on page 10, line 9) and the diagnostic imaging system (first appearing on page 25, line 7).

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "200", first appearing on page 10, line 11; and "146", first appearing on page 13, line 21 (it appears that Fig. 1 has a typo and "145" referring to the alarm output function should actually be "146").

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7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "145" referring to the alarm output function of Fig. 1. As stated above this appears to be a typo.

8. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the following (primarily with respect to Fig. 5): syringe 200 comprising cylinder member 210 and piston member 220 (page 10, line 21, element 200 is not coupled to elements 210 and 220), cylinder member 210 is provided with cylindrical hollow body 211 (page 10, lines 23-24, element 210 is not coupled to element 211), piston member 220 is inserted from the opening into the interior of body 211 (page 11, line 1, element 220 is not coupled to element 211), cylinder member 210 has cylinder flange 213 (page 11, line 2, element 210 is not coupled to element 213), piston member 220 has piston flange 221 (page 11, line 4, element 220 is not coupled to element 221), cylinder flange 213 of liquid syringe 200 (page 11, line 23, element 213 is not coupled to element 200) as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

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number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

10. The above objections are examples of issues discovered by the examiner, however due to the large number of issues and the length of the disclosure, this may not be an exhaustive list. The applicant is requested to thoroughly review the entire application for additional problems.

Specification

11. The disclosure is objected to because of the following informalities: on page 12, line 5, "Injection" appears to be a typo and should read "injection"; on page 16, line 2, "quality" appears to be a typo and should read "quantity"; on page 25, line 3, "CM injection mechanism 117" appears to be a typo and should read "CM injection mechanism 117C". Appropriate correction is required.

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12. The disclosure is objected to because of the following informalities: lengthy specification. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Appropriate action is required.

Claim Objections

13. Claim 7 is objected to because of the following informalities: in line 3 of the claim, the word "difference" appears to be a typo and should read "different".

Appropriate correction is required.

14. Claim 22 is objected to because of the following informalities: the second appearance of the phrase "section entering means" appears to be a typo and should read "region entering means". Appropriate correction is required.

15. Claim 23 is objected to because of the following informalities: the second appearance of the phrase "section entering means" appears to be a typo and should read "region entering means". Appropriate correction is required.

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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17. Claims 1-9, 14-16, and 21-28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claim elements "injection performing means, screen displaying means, condition entering means, condition storing means, image producing means, image displaying means, state detecting means, injection control means, quantity calculating means, time period calculating means, rate storing means, alarm outputting means, review entering means, image storing means, section displaying means, section entering means, region displaying means, condition correcting means, coefficient storing means, coefficient reading means, body entering means, type entering means, concentration storing means, concentration reading means" are means plus function limitations that invoke 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. Throughout the remainder of this office action the following interpretations will be made:

- a. "injection performing means" will be interpreted as the liquid injector, or syringe, or injection head, or a combination thereof, and equivalents thereof.
- b. "screen displaying means" will be interpreted as the touch panel, or screen displaying function, or image displaying function, or computer unit, or a combination thereof, and equivalents thereof.

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- c. "condition entering means" will be interpreted as the condition entering function, or touch panel, or console panel, or control unit, or injection control unit, or a combination thereof, and equivalents thereof.
- d. "condition storing means" will be interpreted as the condition storing function, or RAM, or computer unit, or a combination thereof, and equivalents thereof.
- e. "image producing means" will be interpreted as the image producing function, or computer unit, or a combination thereof, and equivalents thereof.
- f. "image displaying means" will be interpreted as the image displaying function, or image storing function, or computer unit, or touch panel, or a combination thereof, and equivalents thereof.
- g. "state detecting means" will be interpreted as the state detecting function, or computer unit, or a combination thereof, and equivalents thereof.
- h. "injection control means" will be interpreted as the injection control function, or injection control unit, or computer unit, or a combination thereof, and equivalents thereof.
- i. "quantity calculating means" will be interpreted as the quantity calculating function, or computer unit, or a combination thereof, and equivalents thereof.
- j. "time period calculating means" will be interpreted as the state detecting function, or computer unit, or a combination thereof, and equivalents thereof.

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- k. "rate storing means" will be interpreted as the rate storing function, or computer unit, or a combination thereof, and equivalents thereof.
- l. "alarm outputting means" will be interpreted as the alarm output function, or computer unit, or a combination thereof, and equivalents thereof.
- m. "review entering means" will be interpreted as the review entering function, or touch panel, or sub operation panel, or a combination thereof, and equivalents thereof.
- n. "image storing means" will be interpreted as the image storing function, or computer unit, or RAM, or a combination thereof, and equivalents thereof.
- o. "section displaying means" will be interpreted as the section displaying function, or computer unit, or touch panel, or a combination thereof, and equivalents thereof.
- p. "section entering means" will be interpreted as the section entering function, or computer unit, or touch panel, or a combination thereof, and equivalents thereof.
- q. "region displaying means" will be interpreted as the region displaying function, or computer unit, or touch panel, or a combination thereof, and equivalents thereof.
- r. "condition correcting means" will be interpreted as the computer unit, or its components, or a combination thereof, and equivalents thereof.

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- s. "coefficient storing means" will be interpreted as the computer unit, or its components, or a combination thereof, and equivalents thereof.
- t. "coefficient reading means" will be interpreted as the computer unit, or its components, or a combination thereof, and equivalents thereof.
- u. "body entering means" will be interpreted as the touch panel, or computer unit, or its components, or a combination thereof, and equivalents thereof.
- v. "type entering means" will be interpreted as the touch panel, or computer unit, or its components, or a combination thereof, and equivalents thereof.
- w. "concentration storing means" will be interpreted as the computer unit, or its components, or a combination thereof, and equivalents thereof.
- x. "concentration reading means" will be interpreted as the computer unit, or its components, or a combination thereof, and equivalents thereof.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims 1-7, 9, 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application EP 0985421 A2 by Baxter International Inc., hereinafter Baxter, in view of U.S. Patent Application 2002/0007116 A1 by Zatezalo et al., hereinafter Zatezalo.

22. Regarding claim 1, Baxter discloses screen displaying means for displaying a condition screen with its vertical axis representing an injection rate of the liquid and its

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horizontal axis representing an injection time period of the liquid (Baxter, Fig. 22c, status display 38, ramp status icon 142); condition entering means for accepting an input action of at least one injection condition including an injection rate of the liquid relative to the injection time period (Baxter, Figs. 21a-b, volume, time, rate, [0064]: when two of three parameters have been entered); condition storing means for storing the entered injection condition (Baxter, [0035]: enables the user to change the previously selected set of configuration parameters...information from a previous program is retained in the memory); image producing means for producing a condition image having a horizontal width corresponding to the injection time period and including at least the injection rate as text data for each of the injection conditions (Baxter, [0008]: a microprocessor is contained for generating user interface information on the display area, Fig. 22c, status display 38, ramp status icon 142, text information is displayed for the different injection conditions); image displaying means for displaying the at least one produced condition image in the condition screen at a vertical position in association with the injection rate and a horizontal position in association with the injection time period (Baxter, [0008]: a microprocessor is contained for generating user interface information on the display area, Fig. 22c, status display 38, ramp status icon 142, delay time 144, the ramp-up 146, the level delivery 148, and the ramp-down 150, [0074]: the ramp status icon includes a likeness of the delay time, the ramp-up, the level delivery, and the ramp-down periods; each of these likenesses are interpreted as different condition images).

Baxter fails to disclose at least one injection performing means for performing injection of the liquid, state detecting means for measuring at least the elapsed time from the start of the injection of the liquid, and injection control means for controlling the operation of the injection performing means in real time in accordance with the measured elapsed time and the stored injection condition.

Zatezalo discloses at least one injection performing means for performing injection of the liquid (Zatezalo, Fig. 1, injection head unit 38, syringes 40, 42) in order to inject any suitable medium into a patient; state detecting means for measuring at least the elapsed time from the start of the injection of the liquid (Zatezalo, Fig. 3, duration display field 224, [0036]: a clock of elapsed time that starts from zero and spans the duration of the totality of the phases) in order to determine the elapsed time of the procedure; and injection control means for controlling the operation of the injection performing means in real time in accordance with the measured elapsed time and the stored injection condition (Zatezalo, Fig. 1, injection control unit 30, [0048], the "pause" and "hold" phases infer real time control of the injection means) in order to control the injection unit.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the system of Baxter with the system of Zatezalo in order to inject any suitable medium into a patient, determine the elapsed time of the procedure, and control the injection unit, which provides an injection control system that is more readily adaptable to a wider range of contexts.

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23. Regarding claim 2, Baxter discloses quantity calculating means for calculating an injection quantity of the liquid for each of the injection conditions, wherein the image producing means produces the condition image also including the injection quantity as text data (Baxter, Fig. 22c, [0064]: when two of three parameters have been entered, the master processor will calculate the final parameter).

24. Regarding claim 3, Baxter discloses screen displaying means for displaying a condition screen with its vertical axis representing an injection rate of the liquid and its horizontal axis representing an injection quantity period of the liquid (Baxter, Figs. 22c, status display 38, ramp status icon 142, since the vertical axis of the display image is the rate, the horizontal dimension corresponds to information regarding both time and quantity (the area under curve represents quantity)); condition entering means for accepting an input action of at least one injection condition including an injection time period of the liquid relative to the injection quantity (Baxter, Figs. 21a-b, volume, time, rate, [0064]: when two of three parameters have been entered); condition storing means for storing the entered injection condition (Baxter, [0035]: enables the user to change the previously selected set of configuration parameters...information from a previous program is retained in the memory); image producing means for producing a condition image having a horizontal width corresponding to the injection quantity and including at least the injection rate as text data for each of the injection conditions (Baxter, [0008]: a microprocessor is contained for generating user interface information on the display area, Fig. 22c, status display 38, ramp status icon 142, text information

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is displayed for the different injection conditions, since the vertical axis of the display image is the rate, the horizontal dimension corresponds to information regarding both time and quantity (area under curve)); image displaying means for displaying the at least one produced condition image in the condition screen at a vertical position in association with the injection rate and a horizontal position in association with the injection quantity (Baxter, [0008]: a microprocessor is contained for generating user interface information on the display area, Fig. 22c, status display 38, ramp status icon 142, delay time 144, the ramp-up 146, the level delivery 148, and the ramp-down 150, since the vertical axis of the display image is the rate, the horizontal dimension corresponds to information regarding both time and quantity (area under curve), [0074]: the ramp status icon includes a likeness of the delay time, the ramp-up, the level delivery, and the ramp-down periods; each of these likenesses are interpreted as different condition images).

Baxter fails to disclose at least one injection performing means for performing injection of the liquid, state detecting means for measuring at least the injection quantity from the start of the injection of the liquid, and injection control means for controlling the operation of the injection performing means in real time in accordance with the detected injection quantity and the stored injection condition.

Zatezalo discloses at least one injection performing means for performing injection of the liquid (Zatezalo, Fig. 1, injection head unit 38, syringes 40, 42) in order to inject any suitable medium into a patient; state detecting means for measuring at

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least the injection quantity from the start of the injection of the liquid (Zatezalo, Fig. 3, duration display field 226, [0036]: the total volume of fluid that has been expended over the totality of the phases) in order to determine the total fluid injected during the procedure; and injection control means for controlling the operation of the injection performing means in real time in accordance with the detected injection quantity and the stored injection condition (Zatezalo, Fig. 1, injection control unit 30, [0048], the "pause" and "hold" phases infer real time control of the injection means) in order to control the injection unit.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the system of Baxter with the system of Zatezalo in order to inject any suitable medium into a patient, determine the total fluid injected during the procedure, and control the injection unit, which provides an injection control system that is more readily adaptable to a wider range of contexts.

25. Regarding claim 4, Baxter discloses time period calculating means for calculating an injection time period of the liquid for each of the injection conditions, wherein the image producing means produces the condition image also including the injection time period as text data (Baxter, Fig. 22c, [0064]: when two of three parameters have been entered, the master processor will calculate the final parameter).

26. Regarding claim 5, Baxter combined with Zatezalo as stated above discloses wherein the condition entering means accepts an input action of a plurality of the injection conditions for the one injection performing means (Baxter, Figs. 21a-b,

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volume, time, rate, [0064]: when two of three parameters have been entered), the condition storing means stores a plurality of the injection conditions (Baxter, [0035]: enables the user to change the previously selected set of configuration parameters...information from a previous program is retained in the memory), the image displaying means displays the plurality of the produced condition images sequentially arranged horizontally in the condition screen (Baxter, [0008]: a microprocessor is contained for generating user interface information on the display area, Fig. 22c, status display 38, ramp status icon 142, delay time 144, the ramp-up 146, the level delivery 148, and the ramp-down 150, [0074]: the ramp status icon includes a likeness of the delay time, the ramp-up, the level delivery, and the ramp-down periods; each of these likenesses are interpreted as different condition images), the injection control means sequentially controls the operation of the one injection performing means in accordance with the plurality of the injection conditions (Zatezalo, [0035]: the result is a three phase protocol; the injection controller of Zatezalo is capable of sequentially controlling the different phases).

27. Regarding claim 6, Baxter discloses the condition storing means stores a plurality of the injection conditions (Baxter, [0035]: enables the user to change the previously selected set of configuration parameters...information from a previous program is retained in the memory).

Baxter fails to disclose a plurality of the injection performing means, wherein the condition entering means accepts an input action of at least one of the injection

conditions for each of a plurality of the liquids, and the injection control means sequentially controls the operation of the plurality of the injection performing means in accordance with the plurality of the injection conditions

Zatezalo discloses a plurality of the injection performing means (Zatezalo, Fig. 1, syringes 40, 42) in order to inject a plurality of fluids into a patient, wherein the condition entering means accepts an input action of at least one of the injection conditions for each of a plurality of the liquids (Zatezalo, Fig. 3, display fields 210, 220 [0025]: corresponding to contrast medium and flushing medium, respectively; touch fields for the entry of control parameters) in order to program injection conditions for each injectable fluid, and the injection control means sequentially controls the operation of the plurality of the injection performing means in accordance with the plurality of the injection conditions (Zatezalo, [0035]: the result is a three phase protocol) in order to control the different phases of the injection procedure.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Baxter with that of Zatezalo in order to inject a plurality of fluids into a patient, program injection conditions for each injectable fluid, and control the different phases of the injection procedure, which provides an injection control system that is more readily adaptable to a wider range of contexts.

28. Regarding claim 7, Baxter has been discussed above, but fails to disclose a plurality of the injection performing means, wherein the image producing means produces the condition image in a difference color for each of the liquids, and the

image displaying means displays the produced condition image for each of the liquids in a different color in the condition screen.

Zatezalo discloses a plurality of the injection performing means (Zatezalo, Fig. 1, syringes 40, 42) in order to inject a plurality of fluids into a patient, wherein the image producing means produces the condition image in a difference color for each of the liquids (Zatezalo, [0034]: data fields may assume different shades with each medium), and the image displaying means displays the produced condition image for each of the liquids in a different color in the condition screen (Zatezalo, Fig. 3, display fields 210, 220, data fields 214, 216) in order to differentiate between the various phases and fluids being injected.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Baxter with that of Zatezalo in order to inject a plurality of fluids into a patient, and differentiate between the various phases and fluids being injected, which provides an injection control system that is more readily adaptable to a wider range of contexts.

29. Regarding claim 9, Baxter discloses rate storing means for storing an upper limit rate of the liquid injection in advance (Baxter, [0038-0039]: the programming screen prompts the user to enter the rate...if the programmed values exceed an allowable range preprogrammed into the master microprocessor); and an alarm outputting means for outputting an alarm when the injection rate of the stored injection condition exceeds the upper limit rate (Baxter, [0039]: if the programmed values exceed an allowable

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range preprogrammed into the master microprocessor, an out of range alarm will be activated).

30. Regarding claim 21, Baxter discloses wherein the condition storing means stores at least one of the injection condition of previous injection and the injection condition as a default (Baxter, [0066]: a dose infusion retained in the program memory), the image producing means produces the condition image from the injection condition stored before new entry of the injection condition (Baxter, Fig. 22a-c, [0066]: the screen will initially display the parameters from that infusion), and the condition entering means accepts edit operation of the injection condition displayed on the condition screen as an input action of the new injection condition (Baxter, [0079]: personnel can modify the set of configuration parameters using the "change settings" key).

31. Regarding claim 22, Baxter discloses image storing means for storing schematic images of a plurality of body sections of a human body and schematic images of a number of regions to be imaged in relation to each other (Baxter, [0035]: information retained in the memory, capable of storing images), section displaying means for displaying the schematic images of the plurality of body sections in the shape of a human body (Baxter, Fig. 1, display area 23, capable of displaying images), section entering means for accepting an input action to select one of the plurality of displayed body sections (Baxter, Fig. 1, data entry keys 25, Fig. 4, keys 31, 33, 36, [0011]: microprocessor, capable of accepting input action), region displaying means for displaying a schematic image of at least one of the regions to be imaged in association

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with the selected body section (Baxter, Fig. 1, display area 23, capable of displaying images), section entering means for accepting an input action to select the displayed region to be imaged (Baxter, Fig. 1, data entry keys 25, Fig. 4, keys 31, 33, 36, [0011]: microprocessor, capable of accepting input action), the condition storing means stores the injection condition for each of the regions to be imaged (Baxter, [0035]: information retained in the memory, capable of storing multiple injection conditions).

Baxter fails to disclose wherein the injection performing means injects at least a contrast media as the liquid to the patient whose fluoroscopic image is to be imaged by an imaging diagnostic apparatus, the condition entering means accepts an input action of the injection condition for each of the number of regions to be imaged of a human body, the injection control means controls the operation of the injection performing means in accordance with the injection condition of the selected region to be imaged.

Zatezalo discloses wherein the injection performing means injects at least a contrast media as the liquid to the patient whose fluoroscopic image is to be imaged by an imaging diagnostic apparatus (Zatezalo, [0022]: the injection head unit includes contrast media injection syringes) in order to inject contrast medium or any suitable medium used in an imaging process, the condition entering means accepts an input action of the injection condition for each of the number of regions to be imaged of a human body (Zatezalo, [0029-0032]: a three-phase protocol, accepts input for each phase) in order to program injection conditions for each injection fluid and phase, and the injection control means controls the operation of the injection performing means in

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accordance with the injection condition of the selected region to be imaged (Zatezalo, Fig. 1, injection control unit 30, capable of controlling the injection performing means in accordance with injection conditions) in order to control the different phases of the injection procedure.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the system of Baxter with the system of Zatezalo in order to inject contrast medium or any suitable medium used in an imaging process, program injection conditions for each injection fluid and phase, and control the different phases of the injection procedure, which provides an injection control system that is more readily adaptable to a wider range of contexts.

32. Regarding claim 23, Baxter discloses image storing means for storing schematic images of a plurality of body sections of a human body and schematic images of a number of regions to be imaged in relation to each other (Baxter, [0035]: information retained in the memory, capable of storing images), section displaying means for displaying the schematic images of the plurality of body sections in the shape of a human body (Baxter, Fig. 1, display area 23, capable of displaying images), section entering means for accepting an input action to select one of the plurality of displayed body sections (Baxter, Fig. 1, data entry keys 25, Fig. 4, keys 31, 33, 36, [0011]: microprocessor, capable of accepting input action), region displaying means for displaying a schematic image of at least one of the regions to be imaged in association with the selected body section (Baxter, Fig. 1, display area 23, capable of displaying

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images), section entering means for accepting an input action to select the displayed region to be imaged (Baxter, Fig. 1, data entry keys 25, Fig. 4, keys 31, 33, 36, [0011]: microprocessor, capable of accepting input action), condition correcting means for correcting the data of the injection condition in accordance with the selected region to be imaged (Baxter, Fig. 19, weight, Fig. 20, BSA (body surface area), [0064]: when two of three parameters have been entered, the master microprocessor will calculate the final parameter. For example...the master microprocessor will calculate the display rate, since Baxter discloses adjusting injection conditions based on parameters such as body weight and body surface area it would be capable of adjusting injection conditions in accordance with other selected parameters such as a selected region).

Baxter fails to disclose wherein the injection performing means injects at least a contrast media as the liquid to the patient whose fluoroscopic image is to be imaged by an imaging diagnostic apparatus, and the injection control means controls the operation of the injection performing means in accordance with the corrected injection condition.

Zatezalo discloses wherein the injection performing means injects at least a contrast media as the liquid to the patient whose fluoroscopic image is to be imaged by an imaging diagnostic apparatus (Zatezalo, [0022]: the injection head unit includes contrast media injection syringes) in order to inject contrast medium or any suitable medium used in an imaging process, the injection control means controls the operation of the injection performing means in accordance with the corrected injection condition (Zatezalo, Fig. 1, injection control unit 30, capable of controlling the injection

performing means in accordance with injection conditions) in order to control the different phases of the injection procedure.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the system of Baxter with the system of Zatezalo in order to inject contrast medium or any suitable medium used in an imaging process, and control the different phases of the injection procedure, which provides an injection control system that is more readily adaptable to a wider range of contexts.

33. Regarding claim 24, Baxter discloses coefficient storing means for storing a predetermined coefficient for each of the regions to be imaged of the patient (Baxter, [0035]: information retained in the memory, capable of storing coefficient information); and coefficient reading means for reading the data of the coefficient from the coefficient storing means based on the selected region to be imaged (Baxter, [0011]: microprocessor, capable of reading coefficient information from memory), and as stated above Baxter is capable of adjusting injection conditions based on various parameters, therefore Baxter discloses wherein the condition correcting means increases and/or reduces at least one of the injection rate, the injection time period, and the injection quantity in accordance with the read coefficient.

34. Regarding claim 25, Baxter discloses body entering means for accepting data of details of the body of the patient (Baxter, [0063]: allow programming based on body weight or body surface area); and condition correcting means for correcting the data of the injection condition in accordance with the entered data of the details of the body

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(Baxter, Fig. 19, weight, Fig. 20, BSA (body surface area), [0064]: when two of three parameters have been entered, the master microprocessor will calculate the final parameter. For example...the master microprocessor will calculate the display rate).

35. Regarding claim 26, as stated above, Baxter discloses adjusting injection conditions based on body weight and therefore discloses wherein the body entering means accepts the data of the weight of the patient as the details of the body, and the condition correcting means increases and/or reduces at least one of the injection rate, the injection time period, and the injection quantity in accordance with the entered weight.

36. Claims 8 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baxter in view of Zatezalo as applied to claim 1 above, and further in view of U.S. Patent 5,530,796 to Wang, hereinafter Wang.

Baxter combined with Zatezalo as discussed above fails to disclose wherein the condition entering means accepts an input action to move the condition image displayed by the image displaying means upward and/or downward and to move both of lateral ends of the condition image leftward and/or rightward.

Wang discloses wherein the condition entering means accepts an input action to move the condition image displayed by the image displaying means upward and/or downward and to move both of lateral ends of the condition image leftward and/or rightward (Wang, col. 3 lines 50-55: user interface adapter has user interface devices

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such as a touch screen installed on the display, col. 1, lines 48-50: a user interface is provided to move, resize, and edit any object on the display screen) in order to move and edit objects on a display screen.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the user interface system of Wang with the system of Baxter and Zatezalo in order to move and edit objects on a display screen, which provides a user friendly, direct screen manipulation technique.

37. Regarding claim 14, Baxter combined with Zatezalo as discussed above discloses review entering means for accepting an input action of a review instruction (Baxter, [0074]: upon pushing the "view setting" soft key, a ramp infusion parameter screen shows the entered parameters for the infusion).

Baxter seems to show wherein the image displaying means enlarges the text data of the condition image when the review instruction is entered (see time remaining in Fig. 22b (before pressing "view settings") compared to time remaining in Fig. 22c (after pressing "view settings"), the time text appears to be larger). Baxter doesn't explicitly disclose this limitation.

Wang, however, discloses a user interface which would be capable of enlarging text (Wang, col. 3 lines 50-55: user interface adapter has user interface devices such as a touch screen installed on the display, col. 1, lines 48-50: a user interface is provided to move, resize, and edit any object on the display screen).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the user interface system of Wang with the system of Baxter and Zatezalo in order to move, resize, and edit objects on a display screen, which provides a user friendly, direct screen manipulation technique.

38. Regarding claim 15, Baxter discloses further limitation wherein the image producing means produces the text data of the condition image as a combination of a numerical value and its unit (Baxter, Figs. 22c) and it is obvious according to Wang, as stated above, that any object can be resized, therefore Wang discloses the image displaying means enlarges only the text data of the numerical value when the review instruction is entered (Wang, col. 1 lines 48-50, a user interface is provided to move, resize and edit any object on the display).

39. Regarding claim 16, Baxter discloses further limitation wherein the image displaying means displays the text data of the unit outside the condition image when the review instruction is entered (Baxter, Figs. 22c).

40. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baxter in view of Zatezalo as applied to claim 1 above, and further in view of U.S. Patent 5,823,363 to Cassel, hereinafter Cassel.

41. Regarding claim 27, Baxter combined with Zatezalo as discussed above discloses type entering means for accepting data of a type of the contrast media (Baxter, [0032]: medication or solution names are available for selection); and condition correcting

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means for correcting the data of the injection condition in accordance with the entered data of the type of the contrast media (Baxter, Fig. 19, weight, Fig. 20, BSA (body surface area), [0064]: when two of three parameters have been entered, the master microprocessor will calculate the final parameter. For example...the master microprocessor will calculate the display rate, since Baxter discloses adjusting injection conditions based on parameters such as body weight and body surface area it would be capable of adjusting injection conditions in accordance with other selected parameters such as contrast media type).

Baxter combined with Zatezalo as discussed above fails to disclose wherein the injection performing means injects at least a contrast media as the liquid to the patient whose fluoroscopic image is to be imaged by an imaging diagnostic apparatus, and a plurality of the contrast media with different effective components are used.

Cassel discloses wherein the injection performing means injects at least a contrast media as the liquid to the patient whose fluoroscopic image is to be imaged by an imaging diagnostic apparatus, and a plurality of the contrast media with different effective components are used (Cassel, col. 1 lines 12-33: many medical procedures use one or more injectable agents such as contrast media, drugs, fluids, solutions, etc.; the desired contrast agents and different concentrations of the contrast medium can be administered) in order to satisfy the needs of many medical procedures.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the different contrast agents and different concentrations of

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Cassel with the injection performing means of Zatezalo, which is capable of injecting contrast medium, and with the system of Baxter since Cassel discloses the injection of one or more contrast media, drugs, fluids, solutions, etc. as equivalents in a medical procedure.

42. Regarding claim 28, Baxter discloses concentration storing means for storing the concentration for each type of the contrast media and concentration reading means for reading the data of the concentration from the concentration storing means based on the entered data of the type of the contrast media (Baxter, [0035]: information retained in the memory, capable of storing contrast media data, [0011]: microprocessor, capable of reading contrast media data from memory), and as stated above Baxter is capable of adjusting injection conditions in accordance with various parameters, therefore Baxter discloses wherein the condition correcting means increases and/or reduces at least one of the injection rate, the injection time period, and the injection quantity in accordance with the read data of the concentration.

Baxter does not disclose wherein a plurality of the contrast media containing effective components at different concentrations are used.

As stated above, Cassel discloses different contrast agents and different concentrations of contrast medium, therefore discloses wherein a plurality of the contrast media containing effective components at different concentrations are used.

Conclusion

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43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY IMPINK whose telephone number is (571)270-1802. The examiner can normally be reached on Monday through Friday 8:30 am to 4:30 pm EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRADLEY IMPINK/
Examiner, Art Unit 4189

/LONG V. LE/
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